

PATENT

Applicant: Jenkins et al.

Serial No.: 09/730,010

Filing Date: December 4, 2000

Title: Loop Structure Including
Inflatable Therapeutic Device

Group Art Unit: 3772

Examiner: Nguyen

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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APPEAL BRIEF

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¹ Applicant notes for the record that the claims are not limited to the various exemplary embodiments discussed in this Brief. Reference to particular figures, reference numerals and portions of the application are being made solely in order to allow the Board to quickly determine where an exemplary embodiment of each of the claimed inventions is illustrated and described in the application in accordance with 37 C.F.R. § 41.37(c)(1)(v) and MPEP § 1205.02.

I. REAL PARTY IN INTEREST

The real party in interest in the present appeal is Scimed Life Systems, Inc., the assignee of the present application. Scimed Life Systems, Inc. is a wholly owned subsidiary of Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which will directly affect, or be directly affected by, or have a bearing on, the Board's decision in the present appeal.

III. STATUS OF CLAIMS

Claims 14-17, 21-23, 25-30, 38, 39 and 45-51 are pending.

Claims 1-13, 18-20, 24, 31-37 and 40-44 have been canceled.

Claims 16, 26, 30 and 48-51 have been allowed.

Claims 14, 15, 17, 21-23, 25, 27-29, 38, 39 and 45-47 have been rejected under 35 U.S.C. § 103.

Applicant hereby appeals the rejections of claims 14, 15, 17, 21-23, 25, 27-29, 38, 39 and 45-47, which are set forth in the Appendix.

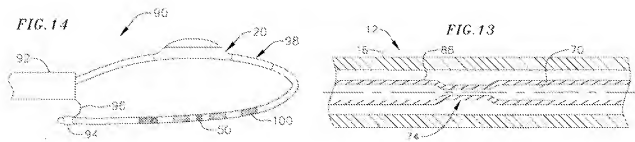
IV. STATUS OF AMENDMENTS

Amendments to the specification and to claims 26 and 30 were filed on October 22, 2009 in response to the Final Office Action. The amendments to the specification and claims have been entered. [Advisory Action dated November 10, 2009; Interview Summary dated November 20, 2009.]

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Independent Claim 14

Independent claim 14 is directed to a “probe.” Referring to Fig. 14, the claimed “probe” comprises “an outer member [92] defining a distal end and including a wall defining an interior bore,” “an elongate body [90] carried within the outer member interior bore, the elongate body defining a proximal region, a distal region and a distal end operably connected [94, 96] to the distal end of the outer member, the elongate body including an internal fluid lumen [30, Fig. 6] extending from the proximal region to the distal region,” and “an inflatable tissue coagulation body [20] supported on the elongate body distal region and operably connected to the internal fluid lumen.” [Spec. at p. 18, ll. 6-11; and p. 8, l. 29 to p. 9, l. 16.]

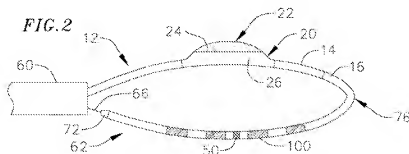


Independent claim 14 also indicates that “the distal region of the elongate body includ[es] a **hinge portion** located proximal of the distal end of the elongate body.” One example of the claimed “hinge portion,” which causes the sharp bend (Fig. 14) at the apex of the loop formed by the “elongate body” [90], is identified by reference numeral [74] in Fig. 13 and is described in the specification in the context of the exemplary embodiment illustrated in Fig. 1.² [Spec. at p. 16, ll. 12-24.]

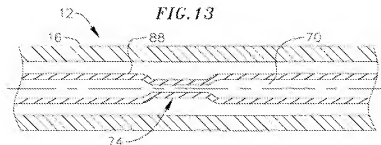
² The specification indicates that the catheter 90 illustrated in Fig. 14 is identical to the catheter 10 (Fig. 1) but for the connection to the distal end of the outer member (e.g. sheath 90). [Spec. at p. 18, ll. 6-11.]

C. Independent Claim 21

Independent claim 21 is directed to a “probe for use with an outer member including a wall defining an interior bore.” Referring to Fig. 2, the claimed “probe” comprises “a tissue coagulation body [20]” and “an elongate catheter tube [12], defining a distal region that supports the tissue coagulation body and a distal end, adapted to be carried within the outer member interior bore and extend outwardly from the interior bore such that the distal region forms a loop [62].” [Spec. at p. 8, l. 29 to p. 9, l. 16; and p. 14, ll. 27-29.] Another exemplary implementation is illustrated in Fig. 14 above.



Referring to Fig. 2 above and Fig. 13 below, independent claim 21 also indicates that “the elongate catheter tube [12] include[s] **a hinge [74]** located proximal of the distal end and **defining the apex [76]** of the loop [62] formed by the distal region, **the apex [76] of the loop having a flexibility that is greater in a bending direction than the flexibility of the portions of the elongate catheter tube that are immediately proximal and distal thereto** and that allows the apex of the loop to be inserted into a pulmonary vein to such an extent that the tissue coagulation body will be substantially aligned with the pulmonary vein ostium.” [Spec. at p. 16, ll. 12-24; Figs. 16a-16b; and p. 19, ll. 11-25.]



VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The rejection of claims 14, 15, 17, 21-23, 25, 27-29, 38, 39 and 45-47 under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 6,332,880 to Yang ("Yang") and U.S. Patent No. 6,076,012 to Swanson ("Swanson") is to be reviewed on appeal.³

³ The explanation of the rejection under 35 U.S.C. § 103 is presented on pages 2-7 of the July 23, 2009 Final Office Action ("Office Action"), with additional explanation provided in the November 10, 2009 Advisory Action ("Advisory Action").

VII. ARGUMENT

A. The Rejection of Claims 14, 15, 17, 38, 39 and 46 Under 35 USC § 103⁴

1. Applicable Standards

The first step in an analysis of a claim under 35 U.S.C. § 103 is to determine what, exactly, is being claimed. To that end, and as noted in MPEP § 2111:

The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard: The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 70 USPQ2d 1827 (Fed. Cir. 2004).

Additionally, "words of the claim must be given their **plain meaning** unless the plain meaning is inconsistent with the specification" and "[o]rdinary, **simple English words** whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, **are construed to mean exactly what they say.**" MPEP § 2111.01, citations omitted, emphasis added. To the extent that the Examiner has taken the position that the word "hinge" is not a simple English word with a clear and unquestionable meaning, one way to determine the meaning that one of skill in the art would ascribe to a particular term is to review analogous prior art references. *Vitronics Corp. v. Conceptoronic, Inc.*, 39 USPQ2d 1573, 1578-79 (Fed. Cir. 1996) ("prior art can often help to demonstrate how a disputed term is used by those skilled in the art"). "Accordingly, the PTO's interpretation of claim terms should not be so broad that it conflicts with the meaning given to identical terms in other patents from analogous art." *In re Cortright*, 49 USPQ2d at 1467.

35 U.S.C. § 103(a) indicates that "[a] patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such

⁴ Claim 14 is an independent claim and claims 17, 38, 39 and 46 depend therefrom.

that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Additionally, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness," *Ex Parte Catan*, 83 USPQ2d 1569, 1573 (Bd. Pat. App. & Int. 2007), citing *In re Kahn*, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

2. Claim Interpretation

The combination defined by independent claim 14 calls for, *inter alia*, an "elongate body" with a distal region that includes "a ***hinge portion*** located proximal of the distal end of the elongate body."

With respect to plain meaning, the plain meaning of the word "hinge" is a device that allows one structure to ***pivot*** relative to another. For example, Stedman's Medical Dictionary defines a "hinge" as "[a] jointed or flexible device that allows the turning or pivoting of a part, such as a door or lid, on a stationary frame."⁵ The plain meaning of a "hinge portion" of an elongate body distal region is, therefore, "a portion of the distal region that allows one part of the distal region to pivot relative to another part of the distal region."

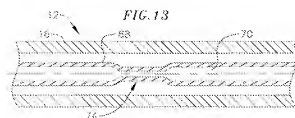
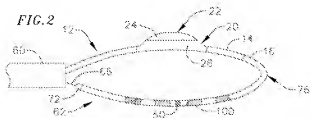
Turning to the manner in which one of skill in the art would interpret the phrase "hinge portion" after reviewing the present specification, the interpretation would clearly correspond to plain meaning. The specification as filed included the following discussion concerning the exemplary embodiment illustrated in Figs. 2 and 13 (reproduced on the following page):

The **flattened portion 74 acts as a hinge** and allows the portion of the catheter body 12 distal to the flattened portion to be bent back into a loop with less force than would otherwise be required. ... **The placement of the flattened portion 74 in the area that will form the apex 76 of the loop 62 also results in a much sharper bend at the apex**, and a more

⁵ hinge. (n.d.). *The American Heritage® Stedman's Medical Dictionary*. Retrieved February 12, 2010, from Dictionary.com website.

compact loop, than would be obtained otherwise. Specifically, conventional loops often have a flattened portion near the proximal end of the loop and tend to assume a generally circular shape when deployed, while the present loop 62 in the exemplary embodiment has a generally flat, elliptical shape resulting from the location of the flattened portion 74.

[Spec. at p. 16, ll. 12-24, emphasis added.] As such, in the context of the exemplary embodiments in the application, a skilled artisan would understand that a “hinge portion” is a structure that allow one part of the catheter body 12 (i.e. the part on which the electrodes 100 are carried) to pivot relative to another part of the catheter body 12 (i.e. the part on which the electrode structure 20 is carried).



Turning to the manner in which the word “hinge” is used in the art generally, U.S. Patent No. 6,016,811 to Knopp (“Knopp”), which is of record in the present application, states in the context of Figs. 9a and 9b that “[t]he curvature of loop 990 is varied throughout loop 990, as ***hinge 980 permits an effective ‘sharp’ bend to be formed in loop 990.***” [Col. 17, ll. 14-17, emphasis added.] In other words, Knopp uses the word “hinge” in the same way as the present application. Knopp also uses the word “hinge” in accordance with plain meaning of the word.

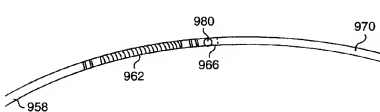


FIG. 9a (partial)

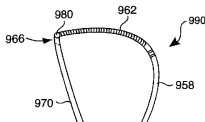
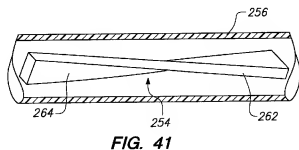
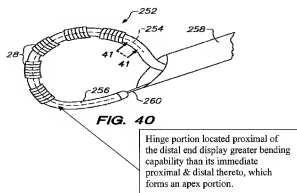


FIG. 9b (partial)

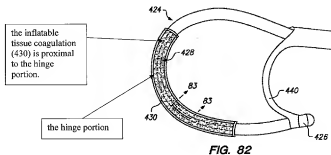
In view of the forgoing, applicant respectfully submits that a “hinge portion” of an elongate body distal region should be interpreted as being “a portion of the distal region that allows one part of the distal region to pivot relative to another part of the distal region.”

3. Yang and Swanson

Yang discloses a myriad of catheters, and the rejection under Section 103 is based on the catheter illustrated in Figs. 40 and 41. [Office Action at p. 2.] Referring first to the marked-up version of Fig. 40 presented in the Office Action (below), Yang discloses an electrode support structure, defined by a spline leg 254 and a sleeve 256, that supports a plurality of electrodes 28. The electrode support structure is bent into a loop 252 when pushed outwardly from a sheath 258. [Col. 20, ll. 22-31.] Referring also to Fig. 41 (below), the spline leg 254 is ***“preformed in a normally twisted condition,”*** the magnitude of the preformed twist is about 90°, the preformed twist is located proximal of the proximal-most electrode 28, and the preformed twist in the spline leg 254 “causes the formed loop structure 252 to bend orthogonally to its main axis.” [Col. 20, ll. 32-42.]



Referring to the marked-up version of Fig. 82 presented in the Office Action (below), Swanson discloses an electrode body 428, including the electrodes 429 (Fig. 83) and porous material 430. Swanson also includes disclosure concerning a spline leg 254 that is identical to that of Yang. [Figs. 38-39; col. 20, ll. 22-42.]



4. Comparison of Claims 14, 17, 38, 39 and 46 to Yang and Swanson

Yang and Swanson do not render the invention defined by independent claim 14 obvious because the combined teachings thereof do not produce the claimed invention. For example, the Office Action has taken two conflicting positions concerning the portion of the Yang electrode support structure corresponds to the claimed "hinge portion." On one hand, the arrow added to Fig. 40 in the Office Action indicates that the that purported "hinge portion" is *distal* of the distal-most electrode 28, while the text of the Office Action (page 2) and Advisory Action both indicate that the purported "hinge portion" is illustrated in Fig. 41, which is a section taken proximal of the proximal-most electrode.⁶ Applicant respectfully submits that one of skill in the art would not consider either of the identified portions of the Yang electrode support structure (or any other portion of the electrode support structure) to be a "hinge portion," i.e. a portion that allows one part of the Yang electrode support structure to pivot relative to another part of the electrode support structure.

As is clearly illustrated in Fig. 40 of Yang (reproduced above), the portion of the electrode support structure identified by the arrow is not a pivot point that allows adjacent parts of the electrode support structure to pivot relative to one another. That region is no less flexible in the bending direction than the proximally and distally adjacent regions, and there is clearly no pivoting of one part relative to another part about the portion of the electrode support structure identified by the arrow in the Office Action. There is simply the smooth curve associated with the electrode support structure being pulled into a loop. Turning to the portion of the electrode support structure that actually includes the twisted section of the spline leg 254, i.e. the portion that is proximal of the proximal-most electrode 28, there is a smooth continuous curve (albeit orthogonal

⁶ The arrow added to Fig. 40 of Yang does not point to the twisted section of the spline leg 254. The twisted section of the spline leg 254 is located at the 41-41 section lines in Fig. 40. [Note that the entire 90° twist is within the area identified by the 41-41 section lines.]

to the main axis) which is caused by the **preformed twist** in the spline leg 254. The region of the electrode support structure with the preformed twist is also no more flexible in the bending direction than the adjacent regions, and there is no pivoting of one part of the electrode support structure in the bending direction relative to another part of the electrode support structure.

The Advisory Action appears to have indicated, in the context of independent claim 21 (discussed in Section VII-D below) that if a structure bends, it necessarily includes a "hinge." To the extent that this position was also taken in the context of claim 14, applicant respectfully submits that this position is incorrect. Most notably, the mere fact that an object bends does lead to the conclusion that it is (or has) a "hinge portion." Although rubber bands, wires and steel beams have respective degrees of flexibility and may be bent, one of skill in the art would not conclude that they have "hinge portions," as this phrase is properly interpreted. Additionally, what is illustrated in Fig. 41 is a pre-twisted portion of the spline leg 254. A preset twist, which holds the adjacent portions in a particular position, is not a "hinge portion."

The teachings of Swanson are identical to Yang with respect to the spline leg 254. Accordingly, Swanson would not have suggested modifications to Yang that would have resulted in the invention defined by independent claim 14.

With respect to the location of the purported "hinge portion" identified by the arrow added to Fig. 82 of Swanson in the Office Action (above), applicant notes for the record that (1) Yang and Swanson⁷ do not suggest a "hinge portion" at any location and (2) the identified location within of the group of electrodes in the electrode body 428 conflicts with the purported "hinge portion" locations identified in the context of Yang, which were proximal of the proximal-most electrode 28 (section 41-41) and distal of the distal-most electrode (added arrow).

The Office Action also failed to present any evidence that (1) there was a predictable solution to a known problem in the art that would have led a skilled artisan from the Yang/Swanson loop with a preformed twist to the invention defined by claim 14,

⁷ The Advisory Action, which states that "Figure 82 of Swanson et al was not relied on for a teaching of the hinge," appears to indicate that the Examiner no longer considers the location identified by the arrow to be a "hinge portion."

or (2) that the use of a “hinge portion” on a catheter that forms a loop by pulling the distal end of catheter toward the sheath or other tubular member was a known technique or the predictable result of a modification based on a known technique, or (3) that there were known design incentives which would have led one of skill in the art from the Yang/Swanson loop with a preformed twist to the invention defined by claim 14. See *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396-97 (2007).

5. Conclusion

In view of the foregoing, applicant respectfully submits that the Office Action failed to establish a *prima facie* case of obviousness with respect to the invention defined by independent claim 14 and that the rejection of claims 14, 17, 38, 39 and 46 under 35 U.S.C. § 103 should be reversed.

B. The Rejection of Claim 15 Under 35 USC § 103

In addition to the elements set forth in independent claim 14, claim 15 indicates that “the inflatable tissue coagulation body is **proximal to** the hinge portion.” Even assuming for the sake of argument that it would have been obvious to employ the Swanson porous electrode body 428 on the electrode support structure illustrated in Figs. 40 and 41 of Yang, the claimed invention would not have been realized. The Swanson electrode body 428 would have been located in the same location as the Yang electrodes 28 after the purportedly obvious modification, and the Yang electrodes 28 are distal of the preformed twist in the spline leg 254.⁸ As such, and referring to Fig. 40 of Yang (reproduced above), the Swanson electrode body 428 would have been located **distal of** the purported “hinge portion,” i.e. **distal of** the preformed twist in the spline leg 254, **not proximal to** the purported “hinge portion.”

⁸ As noted in footnote 6 above, the arrow added to Fig. 40 of Yang does not point to the twisted section of the spline leg 254. The twisted section is proximal to the electrodes 28.

Accordingly, for reasons in addition to those discussed above with reference to independent claim 14, the rejection of claim 15 under 35 U.S.C. § 103 is improper and should be reversed.

C. The Rejection of Claim 45 Under 35 USC § 103

In addition to the elements set forth in independent claim 14, claim 45 indicates that indicates that “the hinge portion has a **flexibility that is greater in a bending direction than** the flexibility of **the portions** of the elongate body that are **immediately proximal and distal thereto**.” Yang and Swanson also fail to teach or suggest this aspect of the claimed combination.

This aspect of the rejection appears to be based on the Examiner’s assertion that because “Figure 41 in the Yang reference illustrates [that] the spline/hinge (254) is bending, it is inherent that the portion of the splin[e]/hinge (254) bending would have a greater flexibility in the bending direction than the flexibility in the proximal/distal portions immediately thereto.” [Advisory Action.] There are a variety of errors associated with this assertion. Most notably, as explained in Yang, the preformed twist in the spline leg 254 cause this portion of the loop structure “to bend orthogonally to its main axis.” In other words, **the bending direction changes with the twist**. Nothing in Yang even remotely suggest that the bending direction flexibility of the electrode support structure associated with the preformed twist (the purported “hinge portion”) is greater than that of the portions immediately proximal and distal thereto. If there is any difference in the bending direction, one of skill in the art would recognize that the twisted portion is less flexible (not more flexible) so that it can force the orthogonal bend.

Also, with respect to the above-quoted assertion of inherency, applicant notes that “[t]o serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with the recourse to extrinsic evidence” and that “such evidence must make it clear that the missing descriptive matter is **necessarily present** in the thing described in the reference.” *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (emphasis added). The Office Action and Advisory Action failed to produce any evidence whatsoever which shows that

the flexibility of the preformed twist in the spline leg 254 is less in the bending direction than that of the portions of the spline leg immediately proximal and distal thereto.

Accordingly, for reasons in addition to those discussed above with reference to claim 14, the rejection of claim 45 under 35 U.S.C. § 103 is improper and should be reversed.

D. The Rejection of Claims 21-23 and 27-29 Under 35 USC § 103⁹

1. Applicable Standards

The applicable standards are the same as those discussed in Section VII-A-1 above.

2. Claim Interpretation

In the combination defined by independent claim 21, “the elongate catheter tube include[es] a ***hinge*** located proximal of the distal end and ***defining the apex of the loop*** formed by the distal region, ***the apex of the loop having a flexibility that is greater in a bending direction than the flexibility of the portions of the elongate catheter tube that are immediately proximal and distal thereto.***”

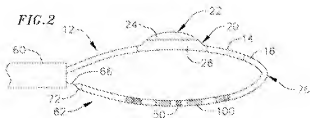
The discussion concerning the proper interpretation of the phrase “hinge portion” in Section VII-A-1 above is applicable to the word “hinge.”

With respect to phrase “apex of the loop,” the plain meaning of the word “apex” is “[t]he usually pointed end of an object; the tip.”¹⁰ Thus, the “apex” of a loop is the “pointed tip end of the loop.” As for the manner in which one of skill in the art would interpret the word “apex” after reviewing the present specification, the interpretation would clearly correspond to plain meaning. Referring to Fig. 2 below, the specification as filed indicated that “[t]he flexible spline 70 includes a flattened portion 74 that is

⁹ Claim 21 is an independent claim and claims 22, 23 and 27-29 depend therefrom.

¹⁰ apex. (n.d.). *The American Heritage® Dictionary of the English Language, Fourth Edition*. Retrieved February 13, 2010, from Dictionary.com website.

located within the portion of the distal member 16 that forms the **apex 76** of the loop 62." [Spec. at p. 16, l. 12-13.]



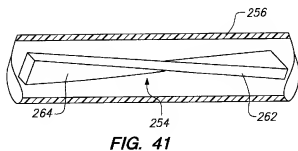
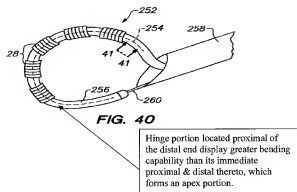
Accordingly, a "hinge ... defining the apex of the loop" should be interpreted as "a portion of the catheter tube, which defines the pointed tip end thereof, that allows one part of the catheter tube to **pivot** relative to another part of the catheter tube."

Turning to the phrase "apex of the loop having a flexibility that is greater in a bending direction than the flexibility of the portions of the elongate catheter tube that are immediately proximal and distal thereto," this is a simple English phrase which means that the catheter tube is more flexible in the bending direction at the apex than it is at the portions adjacent thereto. This definition is confirmed by the application. Note, for example, that the catheter tube 12 is clearly more flexible at the apex 76 than it is where the electrode structure 20 is located and where the electrodes 100 are located, thereby resulting in a sharper bend at the apex. [Fig. 2 above.]

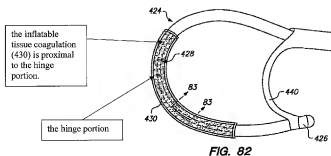
3. Yang and Swanson

Referring first to the marked-up version of Fig. 40 presented in the Office Action, Yang discloses an electrode support structure, defined by a spline leg 254 and a sleeve 256, that supports a plurality of electrodes 28. The electrode support structure is bent into a loop 252 when pushed outwardly from a sheath 258. [Col. 20, ll. 22-31.] Referring also to Fig. 41, the spline leg 254 is "**preformed in a normally twisted condition**," the magnitude of the preformed twist is about 90°, the preformed twist is located proximal of the proximal-most electrode 28, and the preformed twist in the spline leg 254 "causes the formed loop structure 252 to bend orthogonally to its main axis." [Col. 20, ll. 32-42.]

It should also be noted here that the "apex" of the Swanson loop 252 is located approximately at the electrode 28 below reference numeral 28.



Referring to the marked-up version of Fig. 82 presented in the Office Action, Swanson discloses an electrode body 428, including the electrodes 429 (Fig. 83) and porous material 430. Swanson also includes disclosure concerning a spline leg 254 that is identical to that of Yang. [Figs. 38-39; col. 20, ll. 22-42.]



4. Comparison of Claims 21-23 and 27-29 to Yang and Swanson

Yang and Swanson do not render the invention defined by independent claim 21 obvious because the combined teachings thereof do not produce the claimed invention. For example, the Office Action has taken two conflicting positions concerning the portion of the Yang electrode support structure corresponds to the claimed "hinge." On one hand, the arrow added to Fig. 40 in the Office Action indicates that the that purported "hinge" is *distal* of the distal-most electrode 28, while the text of the Office Action (page 3) and Advisory Action both indicate that the purported "hinge portion" is illustrated in Fig. 41, which is a section taken proximal of the proximal-most electrode. Applicant respectfully submits that one of skill in the art would not consider either of the identified portions of the Yang electrode support structure (or any other portion of the

electrode support structure) to be a "hinge," i.e. something that allows one part of the Yang electrode support structure to pivot relative to another part of the electrode support structure.

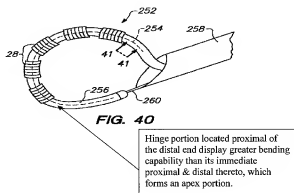
As is clearly illustrated in Fig. 40 of Yang (reproduced above), the portion of the electrode support structure identified by the arrow is not a pivot point that allows adjacent parts of the electrode support structure to pivot relative to one another. That region is no less flexible in the bending direction than the proximally and distally adjacent regions, and there is clearly no pivoting of one part relative to another part about the portion of the electrode support structure identified by the arrow in the Office Action. There is simply the smooth curve associated with the electrode support structure being pulled into a loop. Turning to the portion of the electrode support structure that actually includes the twisted section of the spline leg 254, i.e. the portion that is proximal of the proximal-most electrode 28, there is a smooth continuous curve (albeit orthogonal to the main axis) which is caused by the **preformed twist** in the spline leg 254. The region of the electrode support structure with the preformed twist is also no more flexible in the bending direction than the adjacent regions, and there is no pivoting of one part of the electrode support structure in the bending direction relative to another part of the electrode support structure.

The Advisory Action appears to have taken the position that, because the spline leg 254 bends, it includes a "hinge." Specifically, the Advisory Action stated that "Figure 41 in the Yang reference illustrates the spline (254) is bending" and that "such bending portion serves as a hinge." Applicant respectfully submits that this position is incorrect. Most notably, the mere fact that an object bends does lead to the conclusion that it is (or has) a "hinge." Although rubber bands, wires and steel beams have respective degrees of flexibility and may be bent, one of skill in the art would not conclude that they have "hinges," as this phrase is properly interpreted. Additionally, what is illustrated in Fig. 41 is a pre-twisted portion of the spline leg 254. A preset twist, which holds the adjacent portions in a particular position, is not a "hinge."

Claim 21 also indicates that the "hinge" defines the "apex of the loop" and that the "apex of the loop [has] a flexibility that is greater in a bending direction than the flexibility of the portions of the elongate catheter tube that are immediately proximal and distal

thereto." Nothing in Yang even remotely indicates that the electrode support structure is more flexible in the bending direction both immediately proximally and immediately distally of the arrow added to Fig. 40 (below). Nor does Yang indicate that the electrode support structure is more flexible in the bending direction both immediately proximally and immediately distally of the preformed twist at section line 41-41.

In addition to errors identified in the preceding paragraphs, the two different portions of the Yang electrode support structure identified in the Office Action and Advisory Action as purportedly corresponding to the claimed "hinge," i.e. the portion identified by the arrow and the portion with preformed twist in the spline leg 254 identified with section lines 41-41, do not define the apex of the loop 252. Those portions of the loop 252 would only be the "apex" if (1) the preformed twist was pulled into the sheath 258 or (2) if the electrode support structure was pushed distally relative to the sheath 258 from the position shown until the preformed twist was below the presently illustrated location of reference numeral 28. Nothing in Yang even remotely contemplates such modes of operation.



The teachings of Swanson are identical to Yang with respect to the spline leg 254. Accordingly, Swanson would not have suggested modifications to Yang that would have resulted in the invention defined by independent claim 21.

The Office Action also failed to present any evidence that (1) there was a predictable solution to a known problem in the art that would have led a skilled artisan from the Yang/Swanson loop with a preformed twist to the invention defined by claim 21, or (2) that the use of a "hinge" on a catheter that forms a loop by pulling the distal end of catheter toward the sheath or other tubular member was a known technique or the predictable result of a modification based on a known technique, or (3) that there were known design incentives which would have led one of skill in the art from the Yang/Swanson loop with a preformed twist to the invention defined by claim 21. See *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396-97 (2007).

5. Conclusion

In view of the foregoing, applicant respectfully submits that the Office Action failed to establish a *prima facie* case of obviousness with respect to the invention defined by independent claim 21 and that the rejection of claims 21-23 and 27-29 under 35 U.S.C. § 103 should be reversed.

E. The Rejection of Claim 25 Under 35 USC § 103

In addition to the elements set forth in independent claim 21, claim 25 indicates that “at least the distal region of the elongate catheter tube includes a flexible spline and ***the hinge is defined by a portion of the flexible spline which has a flexibility that is greater in the bending direction than the flexibility of the portions of the flexible spline that are immediately proximal and distal thereto.***”

The cited references fail to teach or suggest such a “spline.” For example, his aspect of the rejection appears to be based on the Examiner’s assertion that because “Figure 41 in the Yang reference illustrates the spline (254) is bending, such bending portion serves as a hinge, it is inherent that hinge portion would have a greater flexibility in the bending direction than the flexibility in the proximal/distal portions immediately thereto.” [Advisory Action.] There are a variety of errors associated with this assertion. Most notably, as explained in Yang, the preformed twist in the spline leg 254 cause this portion of the loop structure “to bend orthogonally to its main axis.” In other words, ***the bending direction changes with the twist.*** Nothing in Yang even remotely suggest that the bend direction flexibility of the portion of the spline leg 254 with the preformed twist (the purported “hinge portion”) is ***greater than*** that of the portions immediately proximal and distal thereto. If there is any difference in the bending direction, one of skill in the art would recognize that the twisted portion is less flexible (not more flexible) so that it can force the orthogonal bend.

Also, with respect to the above-quoted assertion of inherency in the Advisory Action, applicant notes that “[t]o serve as an anticipation when the reference is silent

about the asserted inherent characteristic, such gap in the reference may be filled with the recourse to extrinsic evidence” and that “such evidence must make it clear that the missing descriptive matter is **necessarily present** in the thing described in the reference.” *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (emphasis added). The Office Action and Advisory Action failed to produce any evidence whatsoever which shows that the flexibility of the preformed twist in the spline leg 254 is less in the bending direction than that of the portions of the spline leg immediately proximal and distal thereto.

Accordingly, for reasons in addition to those discussed above with reference to claim 21, the rejection of claim 25 under 35 U.S.C. § 103 is improper and should be reversed.

VIII. CLOSING REMARKS

As applicant has shown above, the rejection under 35 U.S.C. § 103 is improper and should be reversed.

A credit card charge authorization in the amount of \$540 is accompanying the filing of this paper. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

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CLAIMS APPENDIX

14. A probe, comprising:

an outer member defining a distal end and including a wall defining an interior bore;

an elongate body carried within the outer member interior bore, the elongate body defining a proximal region, a distal region and a distal end operably connected to the distal end of the outer member, the elongate body including an internal fluid lumen extending from the proximal region to the distal region, and the distal region of the elongate body including a hinge portion located proximal of the distal end of the elongate body; and

an inflatable tissue coagulation body supported on the elongate body distal region and operably connected to the internal fluid lumen.

15. A probe as claimed in claim 14, wherein the inflatable tissue coagulation body is proximal to the hinge portion.

17. A probe as claimed in claim 14, wherein the inflatable tissue coagulation body comprises a half-balloon tissue coagulation structure.

21. A probe for use with an outer member including a wall defining an interior bore, the probe comprising:

a tissue coagulation body; and

an elongate catheter tube, defining a distal region that supports the tissue coagulation body and a distal end, adapted to be carried within the outer member interior bore and extend outwardly from the interior bore such that the distal region forms a loop, the elongate catheter tube including a hinge located proximal of the distal end and defining the apex of the loop formed by the distal region, the apex of the loop having a flexibility that is greater in a bending direction than the flexibility of the portions of the elongate catheter tube that are immediately proximal and distal thereto and that

allows the apex of the loop to be inserted into a pulmonary vein to such an extent that the tissue coagulation body will be substantially aligned with the pulmonary vein ostium.

22. A probe as claimed in claim 21, wherein the elongate catheter tube defines an exterior and a proximal region, the probe further comprising:

a control element defining a distal portion that extends from the distal end of the elongate catheter tube and a proximal portion extending along the exterior of the elongate catheter tube toward the proximal region of the elongate catheter tube.

23. A probe as claimed in claim 21, wherein the loop defines a length and a height and the flexibility of the hinge is such that the loop length will be at least two times the loop height.

25. A probe as claimed in claim 21, wherein at least the distal region of the elongate catheter tube includes a flexible spline and the hinge is defined by a portion of the flexible spline which has a flexibility that is greater in the bending direction than the flexibility of the portions of the flexible spline that are immediately proximal and distal thereto.

27. A probe as claimed in claim 21, wherein the tissue coagulation body comprises an inflatable tissue coagulation body.

28. A probe as claimed in claim 27, wherein the inflatable tissue coagulation body comprises a half-balloon structure.

29. A probe as claimed in claim 27, wherein the inflatable tissue coagulation body includes micropores.

38. A probe as claimed in claim 14, wherein the wherein the elongate body comprises a catheter body and the outer member comprises a sheath.

39. A probe as claimed in claim 17, wherein the wherein the elongate body comprises a catheter body and the outer member comprises a sheath.

45. A probe as claimed in claim 14, wherein the hinge portion has a flexibility that is greater in a bending direction than the flexibility of the portions of the elongate body that are immediately proximal and distal thereto.

46. A probe as claimed in claim 17, wherein the hinge portion has a flexibility that is greater in a bending direction than the flexibility of the portions of the elongate body that are immediately proximal and distal thereto.

47. A probe as claimed in claim 14, wherein the entire inflatable tissue coagulation body is longitudinally spaced from to the hinge portion.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.